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IFC

PHA 42640.1 (01382/1/US)  
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson et al.

Serial No. 10/828,990

Filed April 21, 2004

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR AND A POTASSIUM ION CHANNEL MODULATOR FOR THE TREATMENT OF CENTRAL NERVOUS SYSTEM DAMAGE

July 28, 2004

1 COMMISSIONER FOR PATENTS  
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SIR:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the

date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,



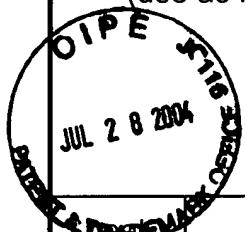
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1 of 4

Attorney Docket No. PHA 42640.1  
(01382/1/US)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
1	1	5,466,823		Talley et al	11/14/1995
	2	5,521,207		Graneto	05/28/1996
	3	5,633,272		Talley et al	05/27/1997
	4	5,932,598		Talley et al	08/03/1999
	5	6,034,256		Carter et al	03/07/2000
	6	6,077,850		Carter et al	06/20/2000
FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number <sup>4</sup>		
7	WO	91/08760		Brigham and Women's Hospital	06/27/1991
8	WO	92/16192		Amgen Inc.	10/01/1992
9	WO	98/03484		Merck Frosst Canada Inc.	01/29/1998
10	WO	00/24719		Abbott Laboratories	05/04/2000

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				Group Art Unit	
				Examiner Name	
Sheet	2	of	4	Attorney Docket No.	PHA 42640.1 (01382/1/US)

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
1	11	ALBERS, "Rationale for Early Intervention in Acute Stroke", American Journal of Cardiology, 1997, 804(4C): 4d-10d	
1	12	GROVER et al, "Anti-Ischemic Effects of the Potassium Channel Activators Pinacidil and Cromakalim and the Reversal of these Effects with the Potassium Channel Blocker Glyburide", Journal of Pharmacology and Experimental Therapeutics, 1989, 251(1): 98-104	
	13	IADECOLA et al, "Reduced Susceptibility to Ischemic Brain Injury and N-Methyl-D-Aspartate-Mediated Neurotoxicity in Cyclooxygenase-2-Deficient Mice", PNAS, 2001, 98: 1294-1299	
	14	IADECOLA et al, "Inducible Nitric Oxide Synthase Gene Expression in Brain Following Cerebral Ischemia", Journal of Cerebral Blood Flow Metabolism, 15: 378-384, 1995	
	15	IADECOLA et al, "Inducible Nitric Oxide Synthase Gene Expression in Vascular Cells After Transient Focal Cerebral Ischemia", Stroke 27: 1373-1380	
	16	KRATZER et al, "Simulation of Primary Haemostasis in Vitro", Haemostasis, 1985, 15:357-362	
	17	LAPCHAK et al, "Neuroprotection by the Selective Cyclooxygenase-2 Inhibitor SC-236 Results in Improvements in Behavioral Deficits Induced by Reversible Spinal Cord Ischemia", 2001, Stroke, 32(5): 1220-1230	
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	19	LIPPERT et al, "Over-Additive Protective Effect of Dizocilpine and NBQX Against Neuronal Damage", European Journal of Pharmacology, 1994, 253: 207-213	

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20	LONGA et al, "Reversible Middle Cerebral Artery Occlusion Without Craniectomy in Rats", Stroke, 20: 84-91, 1989	
21	NAGAYAMA et al, "The Cyclooxygenase-2 Inhibitor NS-398 Ameliorates Ischemic Brain Injury in Wild-Type Mice but not in Mice with Deletion of the Inducible Nitric Oxide Synthase Gene", Journal of Cerebral Blood Flow and Metabolism, 1999, 19(11): 1213-19	
22	NEWMAN, "Aerosols and the Lung: Clinical and Experimental Aspects", Chapter 9 - "Therapeutic Aerosols", Butterworths, London, England, 1984, p. 197-224	
23	NOGAWA et al, "Cyclo-Oxygenase-2 Gene Expression in Neurons Contributes to Ischemic Brain Damage", The Journal of Neuroscience, April 15, 1997, 17(8): 2746-2755	
24	OGAWA et al, "Super-Delayed Changes of Muscarinic Acetylcholine Receptor in the Gerbil Hippocampus Following Transient Ischemia", Advances in Experimental Medicine and Biology, 287: 343-347	
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26	PURCELL et al, "Potassium Channel Openers in Myocardial Ischaemia - Clinical Experience with Nicorandil", Journal of Clinical Cardiology, 1999, 2: 12-14	
27	SARGENT et al, "Effect of Potassium Channel Blockade on the Anti-Ischemic Actions of Mechanistically Diverse Agents", Journal of Pharmacol Experimental Therapeutics, 1991, 259(1): 97-103	
28	STEIN, J. <a href="http://www.psigroup.com/dq/22068A.htm">http://www.psigroup.com/dq/22068A.htm</a> , "ANA: Fampridine May Help Patients with Spinal Cord Injury", October 16, 2002	
29	TANAKA et al, "Post-Ischemic Administration of the Acetylcholinesterase Inhibitor ENA-713 Prevents Delayed Neuronal Death in the Gerbil Hippocampus" Neurochemical Research, 1995, 20(6):663-667	
30	TURSKI et al, "ZK200775: A Phosphonate Quinoxalinedione AMPA Antagonist for Neuroprotection in Stroke and Trauma", PNAS, 1998, 95: 10960-10965	

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	31	VILA et al, "Proinflammatory Cytokines and Early Neurological Worsening in Ischemic Stroke", Stroke, 2000, 31: 2325-2329	
	32	ZHANG et al, "Reduction Focal Cerebral Ischemic Damage by Delayed Treatment with Nitric Oxide Donors", Journal of Cerebral Blood Flow Metabolism, 1994, 14: 574-580	
	33	ZHANG et al, "Aminoguanidine Ameliorates and L-Arginine Worsens Brain Damage From Intraluminal Middle Cerebral Artery Occlusion", 1996, Stroke 27: 317-323	

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